Disclosure as to Expert Witness Simona Miulescu

I. Statement of Opinions, Bases, and Reasons

The following is "a complete statement of all opinions that the government will elicit from the witness in its case-in-chief, or during its rebuttal to counter testimony that the defendant has timely disclosed under [Rule 16](b)(1)(C)," and "the bases and reasons for them." Fed. R. Crim. P. 16(a)(1)(G)(iii).

A. Bases for Testimony

Ms. Miulescu's opinions are based largely upon her more than ten years of experience working as a contractor for the Medicare Program. Ms. Miulescu will help the jury understand what Medicare is, what it pays for, and the mechanics of claim processing and reimbursement.

Ms. Miulescu's opinions are also based on publicly available statutes, regulations, and guidance, some of which is cited throughout this disclosure.

Ms. Miulescu's opinions are also based on the following records, which the prosecution team has provided to Ms. Miulescu and that have previously been provided to the Defendant in this case:

- The Indictment in this case; and
- Medicare claims data for this case.

Ms. Miulescu may review other documents produced to the Defendant and offer opinions on those documents.

B. Opinions and Summary of Anticipated Testimony

The government anticipates that Ms. Miulescu's testimony may cover the following topics and include the following opinions:

1. Information about the Medicare Program generally, including:

   a. Medicare is a federally funded program that provides below-cost health care benefits to people ages 65 years and older, the blind, and the disabled. The Centers for Medicare & Medicaid Services ("CMS") is responsible for the administration of the Medicare Program. Individuals who receive benefits under Medicare are referred to as Medicare "beneficiaries."

   b. Medicare is a "Federal health care program" as defined in Title 42, United States Code, section 1320a-7b(f) and a "health care benefit program" as defined in Title 18, United States Code, section 24(b).

   c. Medicare is divided into four parts: coverage for inpatient care (Part A), coverage for medical items and services (Part B), Medicare Advantage (Part C), and prescription drug benefits (Part D).

d. Physicians, other medical professionals, and other health care providers that provide items and services to Medicare beneficiaries are referred to as Medicare "providers" or "suppliers." To participate in Medicare, providers and suppliers are required to submit an application in which they agree to abide by the laws, policies, procedures, rules, and regulations governing reimbursement. To receive Medicare funds, enrolled providers and suppliers are required to abide by the laws, regulations, and policies governing the program, including, but not limited to, several provisions of the Social Security Act, the regulations promulgated under the Social Security Act, and applicable policies, procedures, rules, and regulations issued by the CMS and its authorized agents and contractors. Medicare manuals and service bulletins describing proper billing procedures, rules, and regulations are made available to providers.

e. A prospective provider also must make representations in its Medicare enrollment application regarding its ownership and management structure as well as the eligibility of its owners, managers, delegated officials, and/or authorized officials to serve in such roles.

f. Medicare relies on providers and suppliers to be truthful in attesting to their obligations and making representations about ownership, management, and other matters in their enrollment application.

g. The CMS assigns a unique identifier to each provider called a National Provider Identifier ("NPI"). The NPI is the standard unique health identifier for health care providers and suppliers and is assigned by the National Plan and Provider Enumeration System ("NPPES"). To enroll in Medicare, a provider must obtain an NPI and furnish it on their application prior to enrolling in Medicare or when submitting a change to their existing Medicare enrollment information. Applying for the NPI is a process separate from Medicare enrollment.

h. If Medicare approves a provider's enrollment application, Medicare assigns the provider a Provider Transaction Access Number ("PTAN"). A provider who is assigned a Medicare PTAN and provides items or services to beneficiaries is able to order, among other things, durable medical equipment and laboratory testing. Claims for items and services are submitted for reimbursement to the Medicare contractor based on these orders.

i. A claim for payment from Medicare is generally required to set forth, among other things, the beneficiary's name, the date the items or services were provided, the beneficiary's diagnosis, the name of the physician or provider who ordered the items or services, and the name of the physician or provider who provided the items or services. Providers convey this information to Medicare by submitting claims electronically using billing codes and modifiers.

j. When submitting claims to Medicare for reimbursement, providers certify that: (1) the contents of the forms are true, correct, and complete; (2) the forms are prepared in compliance with the laws and regulations governing Medicare; and (3) the services purportedly provided, as set forth in the claims, are medically necessary and eligible for reimbursement.

k. Medicare payments are often made directly to the supplier or provider who provided the item or service, rather than to the Medicare beneficiary. Payments occur when the provider submits a claim to Medicare or a Part C plan administrator for payment, either directly or through a billing company.

l. After a claim is submitted and processed, Medicare will generate a remittance advice notice indicating what was submitted, what was processed, and what was paid by Medicare. The remittance advice notice is sent electronically to the provider who billed Medicare in order to provide notice of the adjudicated claim.

m. Medicare regulations require providers to maintain complete and accurate patient medical records reflecting the medical assessment and diagnoses, as well as records documenting actual treatment of the patients to whom services were provided and for whom claims for payment were submitted by the provider. Generally, providers must disclose where such records are kept and maintain them for a period of 6 years. Medicare requires complete and accurate patient medical records so that Medicare can verify that the services were provided as described in the claim form. These records are required to be sufficient to permit Medicare, through its contractors, to review the appropriateness of Medicare payments made to the health care provider.

n. Ms. Miulescu will testify to the claims adjudication process, including the time in which Medicare processes claims and the extent to which claims are, or are not, reviewed by Medicare. She will testify that it is a physical impossibility for every claim to be reviewed before it is paid by Medicare. Instead, Medicare relies on the provider's representation that claims are true and accurate. She will describe Medicare as a "trust-based system."

o. Claims are covered by Medicare if the items or services are accurately described, medically reasonable, medically necessary for the treatment or diagnosis of the patient's illness or injury, documented, and actually provided as represented to Medicare.

p. Medicare publishes guidance regarding what services it does and does not cover in a variety of publications, including National Coverage Determinations ("NCDs"), Local Coverage Determinations ("LCDs"), and the CMS program manuals.

q. Medicare beneficiaries typically have the choice as to which provider will provide services or items prescribed to them. Medicare generally prohibits a provider from directing an order or prescription to a particular company not of the patient's choosing.

r. Medicare does not pay for items or services that are procured through kickbacks and bribes. Ms. Miulescu will provide examples of payment arrangements which would constitute kickbacks and bribes under Medicare regulations such that Medicare would not pay for items or services procured through those payment arrangements, including a provider being paid to refer orders to a particular supplier or laboratory.

2. Medicare coverage and reimbursement for genetic testing, including:

a. As a condition of Medicare payment, a physician or other Medicare provider must certify that any genetic testing services performed were medically necessary as required by Title 42, United States Code, section 1395n(a)(2)(B).

b. Congress has specifically authorized the Medicare program to cover certain routine screening tests. This includes screenings designed to detect existing cardiac conditions, as well as screenings such as mammograms, colonoscopies, PAP smears, and digital prostate exams, which are designed to detect existing malignancies.

c. Ms. Miulescu will contrast routine screening tests expressly covered under statute from genetic testing billed in this case, which is not generally eligible for reimbursement by Medicare on the basis that such testing is not reasonable and not necessary. That is, unlike routine screening tests, cancer genetic testing ("CGx"), pharmacogenetic genetic testing ("PGx"), and cardiovascular genetic testing ("cardio genetic testing") generally are not eligible for reimbursement by Medicare unless specific requirements are met. Among other things, laboratory testing must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A); *see also* 42 C.F.R. § 411.15(a)(1); 42 C.F.R. § 410.10(e).

d. In order for any diagnostic testing to be considered reasonable and necessary, it must be ordered by the physician who is treating the beneficiary, that is, the physician who furnishes a consultation or treats a beneficiary for a specific medical problem and who promptly uses the results in the management of the beneficiary's specific medical problem. Medicare does not cover items and services that are not ordered by the beneficiary's treating physician because the CMS has determined that tests not ordered by the physician treating the beneficiary are not reasonable and necessary. *See* 42 C.F.R. § 410.32(a).

e. Medicare communicates to providers that it does not reimburse for genetic screening services conducted to determine the likelihood that a beneficiary will develop cancer or other conditions in the future. Such testing is considered an "[e]xamination[] performed for a purpose other than treatment or diagnosis of a specific illness, symptoms, complaint, or injury" and is generally excluded from coverage.

f. Medicare will, however, pay for genetic testing performed to aid in the treatment of a beneficiary for a specific medical problem, such as a personal diagnosis of cancer. Generally, however, the test must be ordered by a physician who is treating the beneficiary, and the test results must be promptly used by the physician in the management of the beneficiary's specific medical problem in order to qualify for reimbursement.

g. Ms. Miulescu will also explain Medicare's rules related to providers' record-keeping requirements and requirements related to documenting medical necessity in the patient record in the context of genetic testing. Specifically, Ms. Miulescu will explain that Medicare requires ordering/referring physicians to document medical necessity and other coverage for genetic testing.

h. Ms. Miulescu may provide examples of scenarios under which CGx, PGx, and cardio genetic testing ordered by a provider (1) would not be considered reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of malformed body member or (2) would otherwise be ineligible for reimbursement. For example, CGx, PGx, and cardio genetic testing generally would not

be considered reasonable and necessary if ordered by a provider who was not treating the beneficiary at the time the provider ordered the testing.

i. Generally, genetic testing has lifetime limits. If Medicare covers CGx, PGx, or cardiovascular genetic testing for a beneficiary, the beneficiary typically is not eligible to get coverage/reimbursement for such testing again.

j. Medicare reimburses claims for CGx, PGx, and cardio genetic testing at rates varying from approximately a few hundred dollars to several thousand dollars for a panel of tests. Ms. Miulescu will explain that Medicare does not pay for every potential medical service; rather, many services are expressly excluded from coverage.

k. Claims for genetic testing are typically submitted and paid through interstate wires.

l. Medicare would not cover claims for genetic testing if it knew the claims were based on kickbacks or bribes.

3. Medicare claims data at issue in this case, including:

a. Ms. Miulescu will authenticate Medicare claims data.

b. Ms. Miulescu will apply her knowledge of Medicare rules and regulations regarding claims and reimbursement to the facts of this case.

c. Ms. Miulescu may quantify and summarize the amounts billed and paid for genetic testing based on the Medicare claims data.

d. Ms. Miulescu may convey specific claims information such as the claim number, date of service, billing date, amount billed, procedure codes billed, and associated diagnoses codes reflected in the billing data. Ms. Miulescu may also explain to the jury additional information about the claims that were submitted during the charged conspiracy, as well as information about the beneficiaries' prior treatment history with the referring physicians, as evidenced in claims data.

e. Ms. Miulescu may answer hypothetical questions drawn from the facts of this case regarding how Medicare coverage guidelines are applied in different scenarios.

II. Qualifications

The following is a list of "the witness's qualifications, including a list of all publications authored in the previous 10 years." Fed. R. Crim. P. 16(a)(1)(G)(iii).

Ms. Miulescu is currently employed by SafeGuard Services LLC ("SGS") and supports the Southeast Unified Program Integrity Contractor ("UPIC"). In her current role, Ms. Miulescu is responsible for data analysis, supporting federal law enforcement agencies in cases relating to fraud and abuse, and coordinating and sharing information with the CMS, other contractors, and law enforcement agencies. Ms. Miulescu has over a decade of experience working in this area. During this time, Ms. Miulescu has become familiar with Medicare rules and regulations and has overseen data analysis in support of fraud investigations for Medicare contractors. She is also familiar with analyzing voluminous claims data.

Ms. Miulescu has not authored any publications in the previous ten years.

Ms. Miulescu's CV sets out her qualifications in greater detail. Enclosed with this Disclosure is Ms. Miulescu's current CV.

III. List of Cases

Ms. Miulescu has testified in *United States v. Smith*, 23-cr-80211-Marra/McCabe (S.D. Fla. 2025). Ms. Miulescu has been informed that, if she learns of testimony that should be disclosed under this rule, she is to notify the government.

IV. Approval & Signature

I, Simona Miulescu, have reviewed this Disclosure and approve of its contents.

SIMONA MIULESCU

4/16/25
DATE